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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,019	09/24/2003	Jing Yang	CEN 5014 USNP	2644
27777	7590	07/25/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			KIM, YUNSOO	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 07/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,019

Applicant(s)

YANG ET AL.

Examiner

Yunsoo Kim

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 17-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

5.02

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DETAILED ACTION

1. The art unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Yunsoo Kim, Art Unit 1644, Technology Center 1600.

2. Claims 1-32 are pending.

3. Applicant's election of Group VI, drawn to claims 11-16 in the reply filed on 5/20/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The telephonic species election of SEQ ID NO:2 on 5/27/05 made with Examiner Kosson is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 and 17-32 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 11-16 are under consideration in the instant application.

4. Applicants' IDS filed on 1/23/04 is acknowledged. However, WO 00/76309 and WO 01/78778 have been crossed out as being international search report and partially supplied (upto p.6), respectively.

5. Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

6. The specification is objected to because of the following informalities:

p. 11, the Brief Description of the Figures (p. 11 Fig. 6) should introduce SEQ ID NOs,

p. 21, line 36 typographic error 95-1000%

p. 36, line 35 "Example 4" is not in order. Examples are shown on p. 61.

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7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser executable code. See MPEP 608.01 and 608.01(p).

8. 35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

9. Claims 11-12 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter; a product of nature.

Claims 11-12 as written, do not sufficiently distinguish over antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11-16 are indefinite in that they are dependent on non-elected claims and should be written as independent claims.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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13. Claims 11-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for an antibody binding to the amino acid sequence of SEQ ID NO:2, does not reasonably provide enablement for any antibody binding to at least 80% amino acid sequence identity to SEQ ID NO:2 or antigen binding fragment thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

There is insufficient guidance in the specification as filed as to how the skilled artisan would make and use the antibody to polypeptide having at least 80% amino acid sequence identity to SEQ ID NO:2 or antigen-binding fragment recited in the instant claims. A person of skill in the art would not know which amino acid is essential to retain binding to SEQ ID NO:2. There is insufficient guidance to direct a person of skill in the art to select particular antigen binding fragment. Without detailed direction as to which amino acid is essential to maintain binding to SEQ ID NO:2, a person of skill in the art would not be able to determine which peptides are capable of binding to an antibody or antigen binding fragment without undue experimentation.

Minor structural differences among structurally related compounds can result in substantially different in solubility, adsorption, or biological activities. Therefore, structurally unrelated compounds comprising antibodies or antigen-binding fragment would be expected to have greater differences in their activities. Colman et al. (Research in Immunology, 145(1):33-36, 1994) teach single amino acid changes in an antigen can effectively abolish antibody antigen binding.

Furthermore, Applicant has no working examples demonstrating antigen-binding fragments binding 80% sequence identity to the amino acid SEQ ID NO:2.

Accordingly, the specification is not enabling for any antibody binding to the polypeptide having at least 80% sequence identity to SEQ ID NO:2 and antigen binding fragments because the specification does not adequately disclose how to make polypeptide having at least 80% sequence identity to SEQ ID NO:2 or antigen-binding fragments that are functional for practice of the claimed invention.

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14. Claims 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an antibody capable of binding to the amino acid sequence of SEQ ID NO:2; however, applicant is not in possession of any antibody capable of binding to any polypeptide having at least 80% sequence identity to SEQ ID NO:2 or antigen binding fragment thereof. The phrase "having at least 80% sequence identity to SEQ ID NO:2" includes 8.8×10^8 different amino acid combinations. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 6,211,142 B1 (IDS reference).

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The '142 patent teaches polyclonal, monoclonal, humanized and labeled antibody to gas6 or gas6 variants (cols. 5-6, 11-13, ¹²⁵I labeled example 2, Examples 8, 10) and immobilized antibody to insoluble matrix (Fig 4, captured, example 4, KIRA ELISA).

The '142 patent further teaches a composition of said antibody (col. 19, lines 6-24).

The claims are drawn to antibodies which are capable of binding to any polypeptide which has SEQ ID NO:2 or a peptide 80% identical to SEQ ID NO:2 within the polypeptide. The reason for this is claim 1, non-elected, is drawn to an any polypeptide having 80% sequence identity to SEQ ID NO:2. Since "having" is considered open, the claim encompass any polypeptide of any length that has within its sequence of a peptide 80% identical to SEQ ID NO:2. The prior art teaches antibodies to a polypeptide that has within its polypeptide that is 100% identical to SEQ ID NO:2 (Examples 8, 10, and Fig 7, i.e. gD.gas6-C.IgG)

Thus, reference teachings anticipate the claimed invention.

17. No claims are allowable.

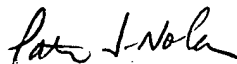
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
July 12, 2005


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600